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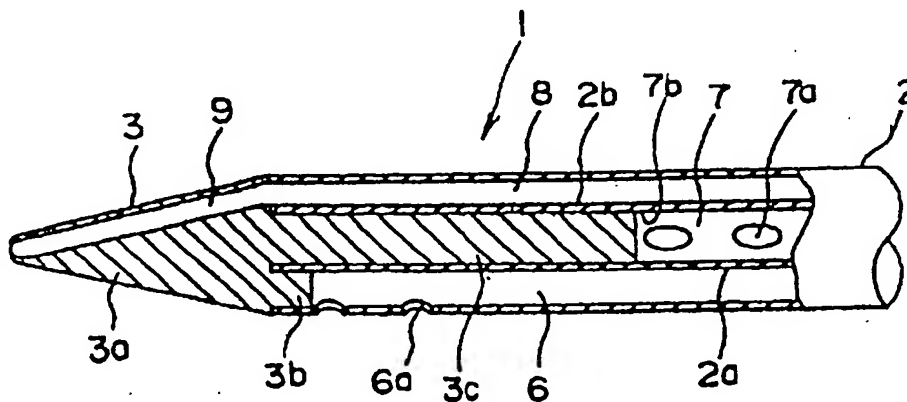
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(54) Title: TRIPLE LUMEN CATHETER



## (57) Abstract

This invention has to do with triple lumen catheters (1), that are used for blood dialysis, for monitoring of temporary circulatory fluids and of central venal pressure (CVP), etc., and more specifically has to do with the structure of triple lumen catheters (1), that are used to allow easy blood extraction during dialysis.

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## TRIPLE LUMEN CATHETER

**Detailed Explanation of Invention**

[0001]

**Field of Technology of this Invention**

This invention has to do with triple lumen catheters (multiple lumen catheters) that are used for blood dialysis, for monitoring of temporary circulatory fluids and of central venal pressure (CVP), etc. and more specifically has to do with the structure of triple lumen catheters that are used to allow easy blood extraction during blood dialysis.

[0002]

**Prior Art**

Examples of triple lumen catheters used for blood dialysis include the inventions disclosed in Patent Disclosure Report Hei 2-209159, Patent Disclosure Report Hei 1-23142, and the United States Patent Report 5,221,256.

[0003]

The triple lumen catheter disclosed in Patent Disclosure Report Hei 2-209159 (Conventional Example 1), as is shown in Figure 3(a), has a main body 21 comprising a tapered tip part 21a and three lumens 22, 23, and 24, and three connecting tubes (not shown) that connect respectively to the three lumens 22, 23, and 24 that are equipped in the base part of the main unit 21. Moreover, two lumens, 22 and 23, of these three lumens, as shown in Figure 3(b), are formed by a dividing wall 22b that is equipped lengthwise and across the inner lumen of main unit 21, where, as shown in Figure 3(a), both lumens 22 and 23 are covered on their tip ends by inserts 25 and 26 that are equipped on the inside near the tips, where the side walls of lumens 22 and 23 at the base side of these inserts 25 and 26 have multiple openings 22a and 23a to allow the lumen to extract or return blood fluids, where the remaining lumen 24 is fabricated by a through hole from the base part to the tip part in the center of main unit 21 and within the dividing wall 21b, and where guide wire 27 passes into this circulatory fluid lumen.

[0004]

When blood dialysis is performed using the triple lumen catheter 20 structured in this way, the catheter is placed within the blood vessel using guide wire 27 that passes through circulation fluid 24 of main unit 21 of the triple lumen catheter 20, a tube connected to the extraction lumen 22 is connected to the blood removal side of the dialysis circuit, and a tube connected to the return lumen 23 is connected to the blood delivery side of the dialysis circuit. However, when the blood dialysis begins, the blood flows into extraction lumen 22 from opening 22a in extraction lumen 22, is sent to the dialysis circuit, is received from the dialysis circuit by the blood return lumen 23, where it flows back into the blood vessel through openings 23a through return lumen 23 to form a dialysis circuit.

[0005]

The triple lumen catheter disclosed in Patent Disclosure Report Hei 1-23142 (Conventional Example 2) is an intravenous catheter. As shown in Figure 4, from the central part of catheter 30 there extends a three-leg inner wall 30a that divides the

catheter into three separate independent inner lumens 31, 32, and 33, where one of these three inner lumens, inner lumen 31, extends to the tip of catheter 30, while the other two inner lumens 32 and 33 end with their respective openings 32a and 32b equipped in the side walls of catheter 30, and are covered by valves 34 and 35 at the tip part side. Furthermore, these three inner lumens 31, 32, and 33 extend beyond the base part of catheter 30 and are attached to inner lumen adaptors (not shown in the Figure) for connecting their respective bases to circulation fluid equipment, etc.

[0006]

Moreover, using the guide wire that is inserted into inner lumen 31, catheter 30 is inserted into the blood vessel where it is secured, and then after the guide wire is removed from inner lumen 31, the inner lumen adaptors that are connected to the respective inner lumens 31, 32, and 33 are connected to fluid delivery devices, CVP monitoring equipment, etc., and thus it is possible to inject the patient with fluid materials through inner lumen 31, etc., at the same time as performing CVP monitoring and/or simultaneously taking blood from the patient's vein.

[0007]

The triple lumen catheter disclosed in United States Patent Report 5,221, 256 (Conventional Example 3) as shown in Figure 5, has a tapered tip part 41a, a main body 41 comprising three lumens 42, 43, and 44, and three connecting tubes (not shown) equipped at the base part of main unit 41 and that connect, respectively, to the three lumens 42, 43, and 44, where two lumens 42 and 43 of these three lumens are formed by a separator wall 41b that is established crosswise and in the axial direction in the inner lumen of main unit 41, where lumen 42 is formed between the base part of main unit 41 and openings 42a that is established in the side wall, where this lumen 42 serves as a blood extraction lumen, where lumen 43, which serves as the blood return lumen, is formed extending from the base part of main unit 41 through the tip part opening 41c, and where the remaining lumen 44, which serves as a circulation fluid lumen is formed in the dividing wall 41b of main unit 41 on one edge of that wall, extending from the base part to opening 44a that is established in the side wall of main unit 41.

[0008]

Moreover, the guide wire that is inserted into circulation fluid lumen 44 is used to insert triple lumen catheter 40 into the blood vessel, where it is held, and while blood dialysis is performed by connecting to a dialysis circuit connection tubes that connect with extraction lumen 42 and return lumen 43, the blood from the dialysis circuit, which was delivered to the dialysis circuit by flowing through extraction lumen 42 from the opening 42a in extraction lumen 42, flows through return lumen 43 and is delivered into the blood vessel through tip opening part 41c.

[0009]

### **Problem Which This Invention Attempts to Solve**

Because, as is shown in Figure 3(b) openings 22a in the extraction lumen 22 in the triple lumen catheter 20 of Conventional Example, 1 as described above, is on the top side of the side wall of main unit 21, or in other words, because the opening is biased to be on only one side of the lumen, then, for example, when blood analysis is performed, the

force delivered to the inside of extraction lumen 22, or in other words, the suction force when opening 22a, which is extracting blood, is close to the blood vessel wall, will cause the space between the blood vessel inner wall and main unit 21 to become narrow, resulting in problems such as inadequate blood extraction flow, and ultimately, with a situation where opening 22a becomes affixed to the inner wall of the blood vessel resulting in faulty blood extraction.

[0010]

Furthermore, similar to Conventional Example 1, in the triple lumen catheter 30 of Conventional Example 2, the opening part 32a of inner lumen 32, which serves as the extraction side, is equipped with a bias that points to only one side of the side wall of catheter 30, and thus the suction will concentrate on only one side so opening part 32a may become affixed to the inside wall of the blood vessel which may result in the occurrence of extraction problems.

[0011]

On top of this, even in the triple lumen catheter 40 of Conventional Example 3, blood extraction for blood dialysis is performed through opening 42a in extraction lumen 42 that is established with a bias to only one side in the side wall of main unit 41, and thus, similar to Conventional Example 1, the blood extraction will cause suction, which will cause opening part 42a to become affixed to the inner wall of the blood vessel, resulting in blood extraction problems, etc.

[0012]

This invention was created to solve problems such as described above for the purpose of providing a high-reliability triple lumen catheter able to prevent with certainty constricted extraction blood flows and extraction problems, etc. through preventing the blockage of extraction openings resulting from the extraction suction force.

[0013]

### **Method For Solving the Problem**

The triple lumen catheter of this invention has a No. 1 lumen and a No. 2 lumen that have a constricted diameter tip part and that are fabricated by a separating wall equipped in the axial direction on the inside, and is equipped with a No. 3 lumen that is parallel to the No. 1 lumen and No. 2 lumen where said No. 3 lumen is equipped on the inside of the side wall so as to connect to the outside through a tip opening part that is equipped on said tip, where either said No. 1 lumen or said No. 2 lumen has at least one pair of opposing side wall openings that connect to the outside and that are perpendicular to the side walls of one of the lumens, and by the provision of a side opening that is perpendicular to the side wall of the other lumen.

[0014]

Moreover, the triple lumen catheter of this invention is not only proved with a separating wall that causes one of the two lumens, the No. 1 lumen or the No. 2 lumen, have a larger cross-sectional area than the other lumen of the pair, but also the lumen with the larger cross-sectional area is equipped with at least one pair of mutually opposing side openings.

[0015]

Moreover the triple lumen catheter of this invention has a thick wall part that extends from said wall part at the position that is opposite to the dividing wall on the inside of either one of the lumens, the No. 1 lumen or the No. 2 lumen, where said No. 3 lumen being equipped within this thick wall part.

[0016]

Moreover the triple lumen catheter of this invention is equipped with a soft tip that comprises a cutting head conical head part that has a wider diameter at its base side, two extending parts that cover the tip side of the lumen that extends from the base part of said head part to the tip region of the side openings of the No. 1 and No. 2 lumens described above, is equipped with a through hole that is connected to the tip part of said No. 3 lumen and that is fabricated running along the conical surface of said head part to the tip opening part equipped in said head part, and is structured with a catheter tip part wherein said soft tip extension parts fit into said No. 1 and No. 2 lumens and where said No. 3 lumen connects to said through hole.

[0017]

In this way, by making either the No. 1 lumen or the No. 2 lumen larger in cross-sectional area than the cross-sectional area of the other lumen, and by establishing in the side walls of the lumen with the larger cross-sectional area at least one pair of mutually opposing side openings that flow to the outside, it is possible to not only prevent the occurrence of inadequate extraction blood flow and blood extraction problems by preventing the blockage of the opening by the side openings contacting the blood vessel inner wall causing blockage by the inner wall, preventing this by extracting blood on both sides of the catheter rather than concentrating the extraction suction force on one side of the catheter when using as the extraction lumen in blood dialysis the lumen equipped with the pair of side openings, but also to perform a highly stabile, high-volume blood extraction for blood dialysis.

[0018]

### Forms of Embodiment of this Invention

Figure 1 is a schematic diagram of a form of embodiment of this invention where cross-sectional diagram A-A, cross-sectional diagram B-B, and Figure 2 shows expanded cross-sectional views of important parts of Figure 1. In these figures, 1 is a triple lumen catheter, comprising a cylindrical main unit 2 that has three lumens 6, 7, and 8 and is made from a synthetic resin material such as, for example, polyurethane, a soft tip 3 structured at the tip of said triple lumen catheter 1 and made from a synthetic resin material such as, for example, polyurethane, and a connection part 4 that is fabricated in a single unit with the base part of main unit 2 and which is equipped with, for example, connection tubes that connect to dialysis circuits, etc., and which are made of synthetic resin materials such as, for example, polyurethane.

[0019]

The main unit 2 of triple lumen catheter 1, as is shown in Figures 1(b) and (c) is equipped with a dividing wall 2a that extends downward from the center of main unit 2

and also in the axial direction, where this main unit 2 is divided by this dividing wall 2a into nearly semicircular halves that form lumens 6 and 7 where one of these lumens, lumen 6, is the blood send lumen for the blood dialysis and is equipped with side opening 6a, which opens to the outside, in the tip part side of the side wall of the conical side wall of main unit 2, while the other lumen, lumen 7, has a larger cross-sectional area than the cross-sectional area of lumen 6, and is the lumen for blood extraction for the blood dialysis that is equipped with at least 1 pair of side openings 7a that open to the outside and that are equipped further towards the base side of main unit 2 than the side opening 6a of lumen 6, and that open on opposite sides of the arc of main unit 2. Moreover, in a position opposite from dividing wall 2a on the inner wall of lumen 7 there is a convex part 7b that protrudes to dividing wall 2a and which forms a thick part on the inner wall of main unit 2, where within this thick wall part 2b is formed a lumen 8, which is circular in cross section with an inner diameter that is nearly the same as the outer diameter of a guide wire (not shown), where this lumen 8 is the circulation fluid lumen that is used for circulation fluid and for CVP monitoring, etc. Furthermore, at the base part of main unit 2, No. 1, No. 2, and No. 3 connecting tubes 5a, 5b, and 5c are connected to lumens 6, 7, and 8, respectively, through a connector 4.

[0020]

As is shown in Figure 2, soft tip three is equipped with a head part 3a that is conical with a wider diameter at the base, and extension parts 3b and 3c that are structured with the same shape as the cross-sectional shape of lumens 6 and 7 respectively and that extend to near the tip parts of side openings 6a and 7a of lumens 6 and 7 from the base part of head part 3a, where these extension parts 3b and 3c not only block the tip sides of lumens 6 and 7 by fitting into lumens 6 and 7, but also head part 3a is formed into a single unit with the tip part side of main unit 2, structuring the tip part of triple lumen catheter 1. Moreover, in head part 3a is equipped through hole 9 that is fabricated along the outside wall of head part 3a until tip opening part 3b that is established in head part 3a and that connects to the tip part of lumen 8, and which has about the same diameter as the inner diameter of lumen 8, and thus lumen 8 opens into through hole 9 when soft tip 3 is joined with the tip part side of main unit 2.

[0021]

No. 1 and No. 2 connection tubes 5a and 5b, as shown in Figure 1(a) are structured from a flexible tube 10a that is made from, for example, a silicone or a soft synthetic resin material such as polyurethane, and which has a connector 10b that connects at its tip to the dialysis circuit connector, and a clamp 10c that can pinch off and close this flexible tube 10a, where the No. 3 connecting tube 5c is structured from a soft tube 11a made from, for example, silicone or a flexible synthetic resin material such as polyurethane, and which has a connector 11b that is connected to the connector of circulation fluid equipment, etc., along with a clamp 11c that is able to pinch off and close this flexible tube 10a.

[0022]

If the form of embodiment structured in this way is used for blood dialysis, the guide wire that is inserted into the blood vessel is inserted into through hole 9 and lumen 8 through tip opening part 3d in soft tip 3 of triple lumen catheter 1, and using this guide wire, etc., triple lumen catheter 1 is inserted into the blood vessel, where it remains. Following this, the guide wire is removed from lumen 8, etc., and after soft tube 11a is



pinched off by clip 11c if No. 3 connection tube 5c, connector 10b of No. 1 connector tube 5a is connected to the supply side of the dialysis circuit, connector 10b of No. 2 connector tube 5b is connected to the extraction side of the dialysis circuit, and dialysis begins.

[0023]

When the blood dialysis begins, the blood fluids flow into lumen 7 from side openings 7a that open into lumen 7, and are sent to the dialysis circuit, and the blood fluids from the dialysis circuit are sent into through lumen 6 and into the blood vessel through side openings 6a that opens into lumen 6. At this time, the blood fluids are drawn into lumen 7 through the 1 pair or more of side openings 7a that are equipped opposite each other in the side walls of main unit 2, or in other words, are drawn in from two different directions.

[0024]

After the blood has been dialyzed, then if the triple lumen catheter 1 is maintained within the blood vessel, connector 10b of the No. 1 connector tube 5a, and connector 10b of the No. 2 connector tube 5b are removed from the dialysis circuit, lumens 6 and 7 are flushed with a heparin saline solution, and a heparin lock is created.

[0025]

In this way, the blood extraction in the blood dialysis is performed through at least 1 pair of side openings 7a that are established opposite each other in the side walls of main unit 2 and that open into lumen 7, or in other words, the blood extraction is performed through side openings 7a that are established in two different directions relative to lumen 7, and thus the suction force on side openings 7a does not concentrate in a single direction as it did in the past (i.e. the direction where the side openings are), but rather there is suction on both sides, making it possible to maintain main body 2 with stability in nearly the center of the blood vessel. Using this process, it is possible to prevent inadequate blood extraction due to the space between the inner wall of the blood vessel and main unit 2 becoming constricted when the force of the suction of the blood fluids causes side opening 7a to move near to the inner wall of the blood vessel, and making it possible to prevent side opening 7a from becoming stuck to the inner wall of the blood vessel which leads to problems with failed blood extraction. This makes it possible to obtain a highly reliable triple lumen catheter 1 that is able to produce a stable and secure blood extraction.

[0026]

Moreover, because the cross section of lumen 7 is formed larger than the cross section of lumen 6 it is possible to obtain an increased blood extraction flow, not only making it possible to reduce the load on the patient, but making it possible to perform smooth, rational dialysis because it is possible to extract blood with certainty using the pair of opposing side openings 7a provided.

[0027]

Furthermore, by fabricating lumen 8 in the thick wall part 2b of main unit 2 it becomes possible to position the pair of side openings 7a equipped in the side walls of main unit 2 at nearly 180 degrees opposite each other, making it possible to make the side openings

7a larger, thus making it possible to secure the extraction blood flow, and making it possible to prevent the blood vessel walls from obstructing the blood vessel.

[0028]

Moreover, while the form of embodiment described above was explained assuming the tip part of triple lumen catheter 1 was structured from soft tip 3, soft tip 3 may also be fabricated as a single unit with main body 2, or the triple lumen catheter 1 tip part may be structured from the tip part of main unit 2.

[0029]

### Effects of the Invention

As described above, the triple lumen catheter of this invention has a No. 1 lumen and a No. 2 lumen that have a constricted diameter tip part and that are fabricated by a separating wall equipped in the axial direction on the inside, and is equipped with a No. 3 lumen that is parallel to the No. 1 lumen and No. 2 lumen where said No. 3 lumen is equipped on the inside of the side wall so as to connect to the outside through a tip opening part that is equipped on said tip, where either said No. 1 lumen or said No. 2 lumen has at least one pair of opposing side wall openings that connect to the outside and that are perpendicular to the side walls of one of the lumens, and by the provision of a side opening that is perpendicular to the side wall of the other lumen. Thus it is possible to prevent inadequate blood extraction due the side opening move near to the inner wall of the blood vessel, and making it possible to prevent the side opening from becoming stuck to the inner wall of the blood vessel which leads to problems with failed blood extraction, thus making it possible to obtain a highly reliable triple lumen catheter 1 that is able to produce a stable and secure blood extraction.

[0030]

Moreover, the triple lumen catheter of this invention is not only proved with a separating wall that causes one of the two lumens, the No. 1 lumen or the No. 2 lumen, have a larger cross-sectional area than the other lumen of the pair, but also the lumen with the larger cross-sectional area is equipped with at least one pair of mutually opposing side openings, making possible to obtain a triple lumen catheter capable of an increased blood extraction flow, not only making it possible to reduce the load on the patient, but making it possible to perform smooth, rational dialysis because it is possible to extract blood with certainty using the pair of opposing side openings 7a provided.

[0031]

Moreover the triple lumen catheter of this invention has a thick wall part that extends from said wall part at the position that is opposite to the dividing wall on the inside of either one of the lumens, the No. 1 lumen or the No. 2 lumen, where said No. 3 lumen being equipped within this thick wall part. This makes it possible to secure a large extraction blood flow, and makes it possible to prevent with certainty the side openings from being obstructed by the blood vessel side walls.

[0032]

Moreover the triple lumen catheter of this invention is equipped with a soft tip that comprises a cutting head conical head part that has a wider diameter at its base side, two extending parts that cover the tip side of the lumen that extends from the base part of said head part to the tip region of the side openings of the No. 1 and No. 2 lumens described above, is equipped with a through hole that is connected to the tip part of said No. 3 lumen and that is fabricated running along the conical surface of said head part to the tip opening part equipped in said head part, and is structured with a catheter tip part wherein said soft tip extension parts fit into said No. 1 and No. 2 lumens and where said No. 3 lumen connects to said through hole. This makes it possible to use a simple structure that does not require a separate insert to be put into the lumen, etc. in order to prevent dead space in the lumen, and makes it possible to structure into conical shapes the soft tips that have been provided at the tips of conventional catheters, thus making it possible to obtain a triple lumen catheter that greatly reduces the amount of labor by making the soft tip more secure.

## Simple Explanation of Drawings

### Figure 1

This is a schematic diagram of the form of embodiment of this invention with the associated A-A cross-sectional diagram and B-B cross-sectional diagram.

### Figure 2

This is an expanded cross-sectional diagram of important parts of Figure 1.

### Figure 3

This is an expanded cross-sectional view and a C-C cross-sectional diagram of the important parts of a conventional triple lumen catheter.

### Figure 4

This is an expanded cross-sectional view and a D-D cross-sectional diagram of the important parts of another conventional triple lumen catheter.

### Figure 5

This is an expanded cross-sectional view and a E-E cross-sectional diagram of the important parts of yet another conventional triple lumen catheter.

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**DOCUMENT NAME:           DETAIL DOCUMENT**

**NAME OF INVENTION:       TRIPLE LUMEN CATHETER**

## **Range of Patent Claims**

### **Claim 1**

A triple lumen catheter characterized by having a No. 1 lumen and a No. 2 lumen that have a constricted diameter tip part and that are fabricated by a separating wall equipped in the axial direction on the inside, and equipped with a No. 3 lumen that is parallel to the No. 1 lumen and No. 2 lumen where said No. 3 lumen is equipped on the inside of the side wall so as to connect to the outside through a tip opening part that is equipped on said tip, where either said No. 1 lumen or said No. 2 lumen has at least one pair of opposing side wall openings that connect to the outside and that are perpendicular to the side walls of one of the lumens, and by the provision of a side opening that is perpendicular to the side wall of the other lumen.

### **Claim 2**

The triple lumen catheter of Range of Patent Claims 1 characterized not only by the provision of a separating wall that causes one of the two lumens, the No. 1 lumen or the No. 2 lumen, have a larger cross-sectional area than the other lumen of the pair, but also by the lumen with the larger cross-sectional area being equipped with at least one pair of mutually opposing side openings.

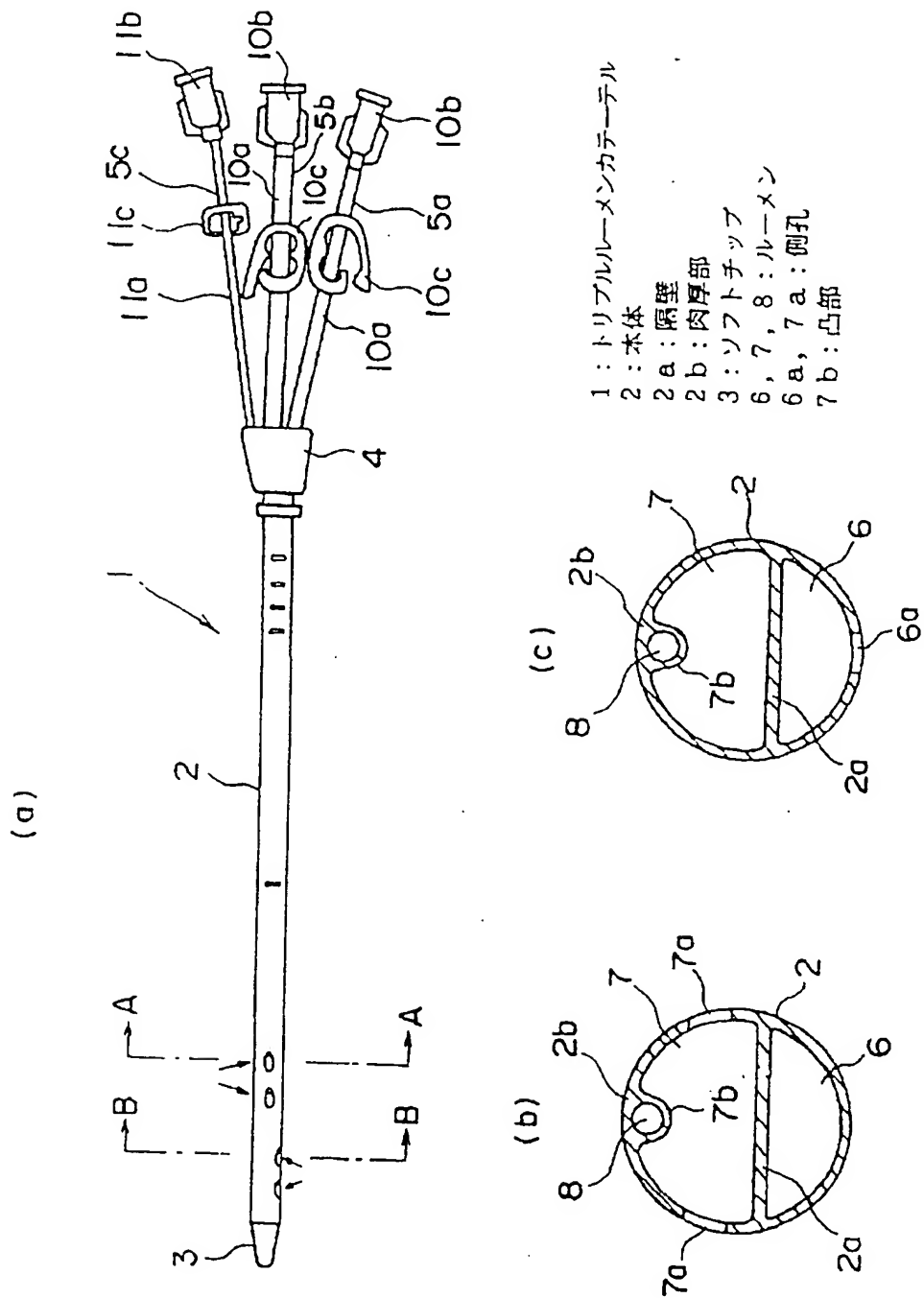
### **Claim 3**

The triple lumen catheter of Range of Patent Claims 1 and 2 characterized by the formation of a thick wall part that extends from said wall part at the position that is opposite to the dividing wall and on the inside of either one of the lumens, the No. 1 lumen or the No. 2 lumen, and by said No. 3 lumen being equipped within this thick wall part.

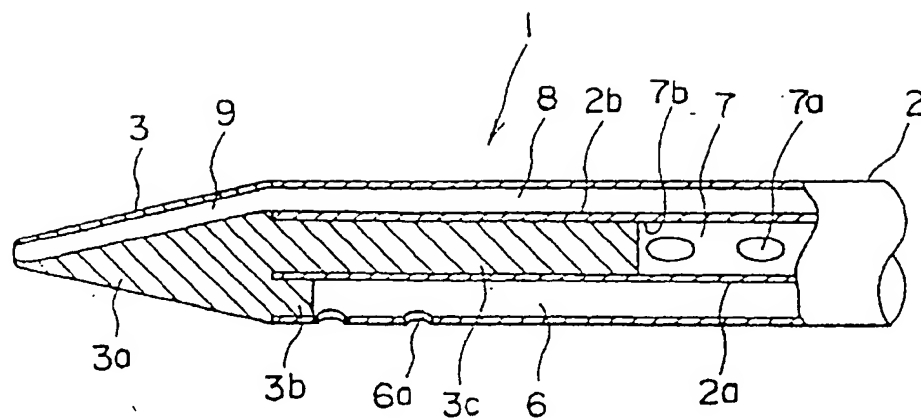
### **Claim 4**

The triple lumen catheter of Range of Patent Claims 1, 2, and 3 characterized by being equipped with a soft tip that comprises a cutting head conical head part that has a wider diameter at its base side, two extending parts that cover the tip side of the lumen that extends from the base part of said head part to the tip region of the side openings of the No. 1 and No. 2 lumens described above, by being equipped with a through hole that is connected to the tip part of said No. 3 lumen and that is fabricated running along the conical surface of said head part to the tip opening part equipped in said head part, and by being structured with a catheter tip part wherein said soft tip extension parts fit into said No. 1 and No. 2 lumens and where said No. 3 lumen connects to said through hole.

【図 1】



[ 図 2 ]

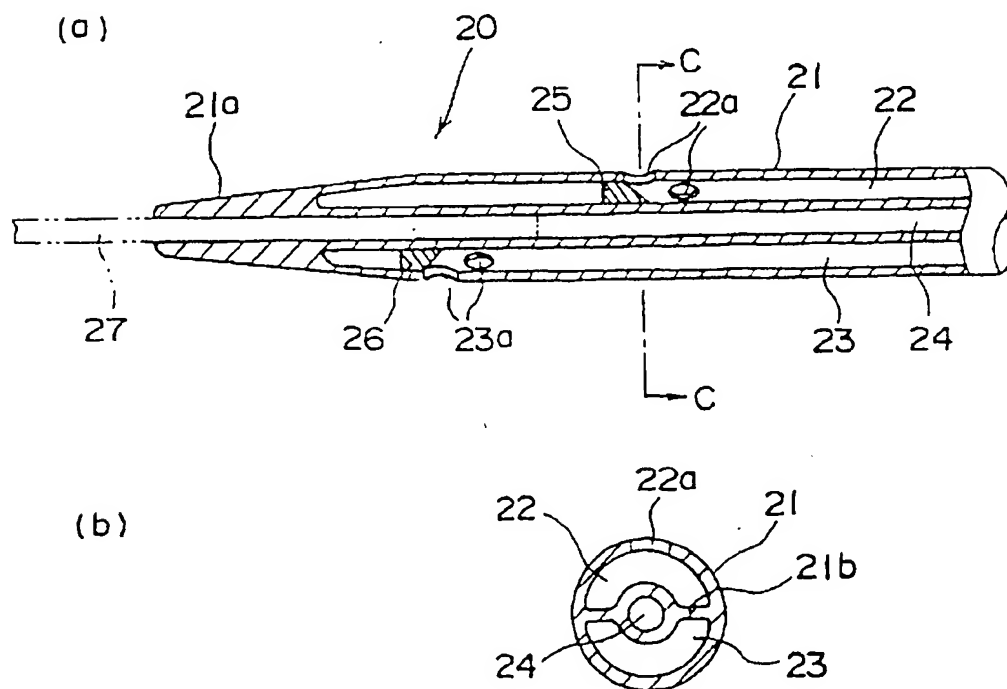


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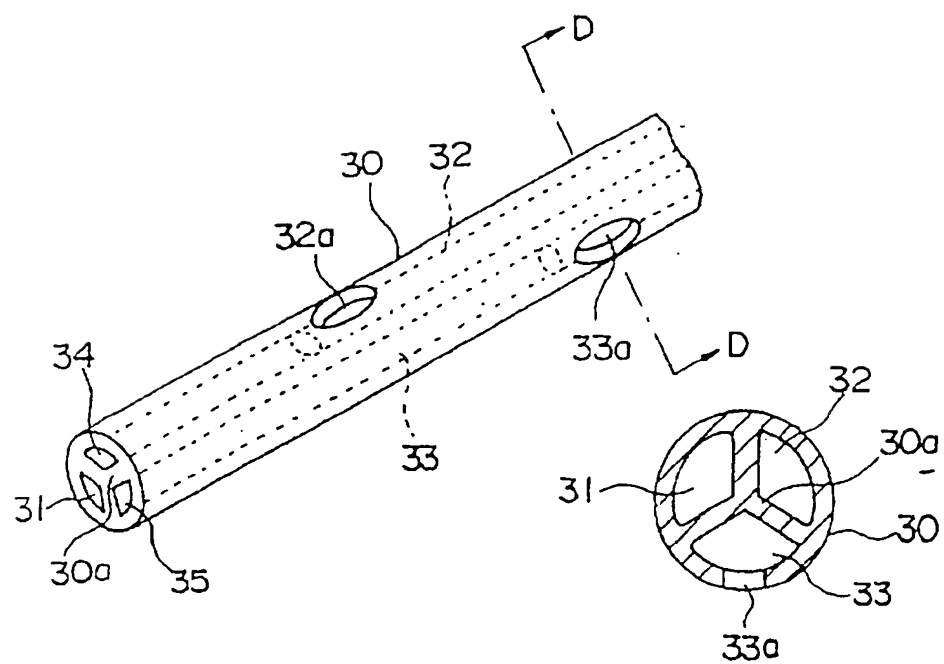
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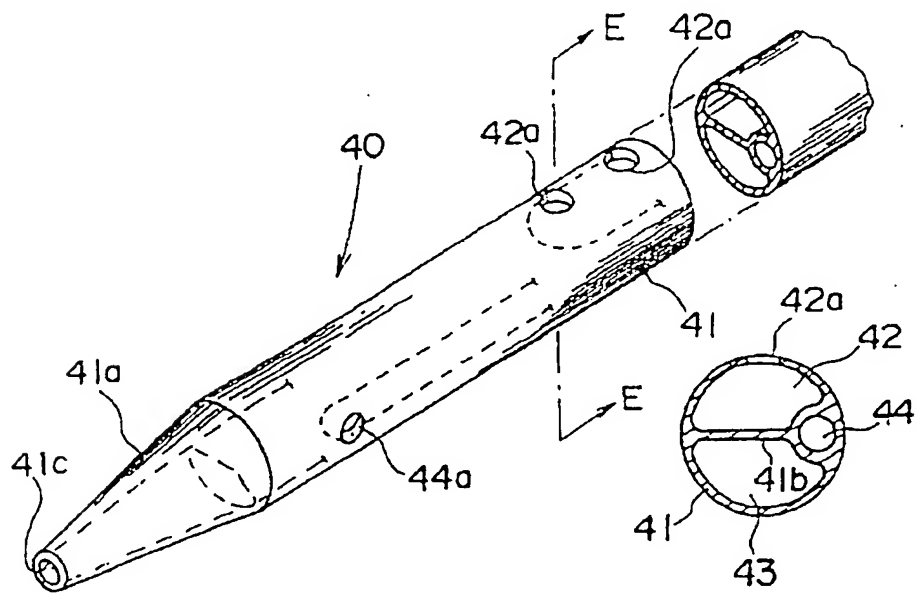
[ 図 3 ]



[ 図 4 ]



[ 図 5 ]



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/06029

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 3/00, 25/00

US CL : 604/43, 280

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/43, 280, 264, 281-283, 44-45

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,221,255 A (MAHURKAR et al) 22 June 1993, see figures 38-44	1-3 ----- 4
Y	US 5,195,962 A (MARTIN et al) 23 March 1993, see figure 17.	4
A	US 5,451,206 A (YOUNG) 19 September 1995, see entire document	1-4
A	US 5,378,230 A (MAHURKAR) 03 January 1995, see entire document	1-4
A	US 5,403,291 A (ABRAHAMSON) 04 April 1995, see entire document	1-4



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

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